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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/788,746	02/26/2004	Jonathan Weston	I 98376 US D1	6112

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PATENT DEPARTMENT
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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/788,746	WESTON ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed October 23, 2006 is acknowledged and entered. Claims 14-18 are pending and under examination. This Office action is non-final in view of the new grounds of rejection. Any inconvenience is regretted.

Response to Amendment

The objection to the specification is withdrawn in view of Applicant's amendment to the specification. The objections to claims 14-18 are withdrawn in view of the amendment to claims 14-18.

Claims Summary

The claims are drawn to a recombinant E2 protein of Fish Pancreatic Disease virus (FPDV). Applicant's use of the term "recombinant" appears to refer to the method by which the E2 protein may be obtained (page 7, lines 21-23, and page 9, lines 3-4). The E2 protein itself is understood to be intact. Specifically, the E2 protein comprises SEQ ID NO: 6. The E2 protein is used as a pharmaceutical, a vaccine, or a diagnostic.

Claim Rejections - 35 USC § 112

Claims 16 and 17 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

invention. The claims are drawn to a pharmaceutical composition and a vaccine comprising the recombinant protein of SEQ ID NO: 6, and a pharmaceutically acceptable carrier. Pharmaceutical compositions and vaccines require evidence of a therapeutic benefit, and protection, respectively. The specification as filed does not appear to be enabled for either a composition conferring a therapeutic benefit or protection against pancreatic disease (FPDV) in fish.

Applicant's arguments have been carefully considered but fail to persuade. Applicant's substantive arguments are primarily directed to the following:

- Applicant argues that the knowledge available to the skilled artisan at the time of filing date of the instant invention is evidenced at page 17, lines 22-25 of the instant specification. Applicant asserts that experimental tests and analytical methods to enable the determination of whether a given pharmaceutical composition or vaccine was effective against FPD virus were available at the time of filing. Applicant points to EP 0712926 A2 (Exhibit A submitted 10/23/06. herein, "the '926 application"), which details data relating to challenge experiments of fish vaccinated with formalin-inactivated PD virus. The protocol, histological and viral scoring are described in the '926 application.
    - In response to Applicant's arguments, the Office does not dispute what was known in the art at the time of filing the instant application. However, Applicant's disclosure does not provide any information about their standard challenge experiments (conditions of the experiment and data collected). All that Applicant offers to the public is their assessment of the undisclosed data surrounding the challenge experiments: protection and therapeutic benefit.

Without knowing the conditions of the challenge experiments (formulations of the E2 protein, adjuvanting, route of administration, frequency of administration, controls, etc.) one cannot conclude that the claimed E2 proteins are effective vaccine or therapeutics.

- While Applicant points to other sources for the conditions of their experiment, Applicant has not accounted for the difference between using a subunit (E2) versus a whole virus construct as described in the '926 application. The only evidence that the '926 application provides is that one of skill in the art is aware of how to conduct a challenge experiment with whole virus FPDV and analyze the results. One cannot relate to Applicant's undisclosed "standard" challenge experiments with those described in the '926 application.

- Applicant asserts that the specification need not disclose what is well known to the skilled artisan. Applicant also asserts that the state of the art existing at the time of filing is used to determine whether a particular disclosure is enabling. Applicant asserts that they have employed a standardized challenge model and scored results in the ordinary way; significant levels were calculated from Kruskal-Wallis one-way analysis of variance (page 17, lines 21-22 of specification). Applicant concludes that the techniques do not need to be explicitly described if they are well known to the skilled artisan.

  - In response to Applicant's arguments, the state of the art at the time of filing is not the only factor in the legal analysis for enablement. The '926 application is evidence of the state of the art for whole virus vaccination. This is not the same type of vaccination as the instant subunit vaccination. The other factors that are

considered in the Wands analysis include guidance from the specification and working examples. Again, the working examples that Applicant refers to are not provided in such a way that one can independently analyze the results obtained from the challenge experiments. Applicant merely provides their conclusion about the challenge experiments without providing any data. The fact that one skilled in the art can analyze data does not account for the lack of information in the instant specification. Since Applicant has performed "standard" challenge experiments and "ordinary" analyses, then Applicant is invited to submit that information.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(*New Rejection*) Claims 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over McLoughlin *et al.* (EP 0712926 A2, "McLoughlin") in view of Schlesinger et al. (Reference AS cited in IDS filed 2/26/04). The claims are summarized above. Note that the claims are rejected for their structural features, not the intended non-enabled uses of treatment and prophylaxis.

McLoughlin discloses the use of envelope polypeptides of FPDV as vaccines and diagnostics (page 3, lines 25-29, and claims 20-27 of McLoughlin). McLoughlin discloses that

the vaccine is added directly to the water (pharmaceutically acceptable carrier) containing the fish (page 4, lines 45-48). Although McLoughlin does not specifically mention the envelope protein, E2, of the toga-like virus (McLoughlin, page 2, line 48), Schlesinger teaches that togaviruses have glycoproteins E1 and E2 (page 826, first column). It would have been obvious to use the envelope proteins, E1 and/or E2 (taught by Schlesinger), as suggested by McLoughlin (page 3, lines 25-29). One would have been motivated to use the E2 protein because, as taught by Schlesinger, E2 is one of the envelope proteins of togaviruses. Given that McLoughlin discloses the availability of the FPDV envelope proteins, one would have had a reasonable expectation of success that the E2 protein of togaviruses would have been present in the toga-like virus FPDV. With regard to SEQ ID NO: 6, this is an inherent property of the FPDV E2 protein. Although Applicant elucidated the sequence, the sequence is a natural feature of the E2 protein and is entirely expected to be the sequence of the protein taught by McLoughlin in view of Schlesinger. Therefore, the structural features of the claimed embodiments are obvious over the prior art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B Chen 1/5/07

STACY B. CHEN
PRIMARY EXAMINER